

(b) Manufacturers have the responsibility to identify devices that meet the criteria for tracking and to initiate tracking. By way of illustration and to provide guidance, FDA has set out below a list of example devices it regards as subject to tracking under the criteria set forth in this regulation.

(1) Permanently implantable devices.

21 CFR	Classification
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter
(no cite)	Total temporomandibular joint prosthesis.
(no cite)	Glenoid fossa prosthesis.
(no cite)	Mandibular condyle prosthesis.
(no cite)	Interarticular disc prosthesis (interpositional implant).
870.3545	Ventricular bypass (assist) device
870.3610	Implantable pacemaker pulse generator
870.3680	Cardiovascular permanent pacemaker electrode
870.3800	Annuloplasty ring
870.3925	Replacement heart valve
(no cite)	Automatic implantable cardioverter/defibrillator
878.3720	Tracheal prosthesis
882.5820	Implanted cerebellar stimulator
882.5830	Implanted diaphragmatic/phrenic nerve stimulator
(no cite)	Implantable infusion pumps

(2) Life-sustaining or life-supporting devices used outside device user facilities

21 CFR	Classification
868.2375	Breathing frequency monitors (apnea monitors) (including ventilatory efforts monitors)
868.5895	Continuous ventilator
870.5300	DC-defibrillator and paddles

(c) FDA designates the following devices as subject to tracking. Manufacturers must track these devices in accordance with this part.

21 CFR	Classification
876.3350	Penile inflatable implant
878.3530	Silicone inflatable breast prosthesis
878.3540	Silicone gel-filled breast prosthesis
876.3750	Testicular prosthesis, silicone gel-filled
(no cite)	Silicone gel-filled chin prosthesis
(no cite)	Silicone gel-filled angel chik reflux valve
880.5725	Infusion pumps

(d) FDA, when responding to pre-market notification submissions and approving premarket approval applications, will notify the sponsor that FDA believes the device meets the criteria of section 519(e)(1) and therefore should be tracked. FDA will also, after notifying the sponsor, publish a notice in the FEDERAL REGISTER announcing that FDA believes a new generic type of de-

vice is subject to tracking and soliciting comment on FDA's position. If the device is a new generic type of device not already on the example list above, FDA will add it to this list.

[58 FR 43447, Aug. 16, 1993, as amended at 58 FR 43455, Aug. 16, 1993; 59 FR 15052, Mar. 31, 1994.]

§ 821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside a device user facility that are intended for use by a single patient over the life of the device and permanent implants that are tracked devices, after distribution to or implantation in a patient:

(i) The lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the

explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside device user facilities that are intended for use by more than one patient and that are tracked devices, after the distribution of the device to the multiple distributor:

(i) The lot model number, batch number, serial number of the device or other identifier necessary to provide for effective tracking of the device;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device;

(v) The location of the device;

(vi) The date the device was provided for use by the patient;

(vii) The name, address, and telephone number of the prescribing physician; and

(viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the fol-

lowing into the standard operating procedure:

(1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;

(2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and

(3) A quality assurance program that includes an audit procedure to be run for each device product subject to tracking, at not less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter. This audit procedure shall provide for statistically relevant sampling of the data collected to ensure the accuracy of data and performance testing of the functioning of the tracking system.

(d) When a manufacturer becomes aware that a distributor, final distributor, or multiple distributor has not collected, maintained, or furnished any record or information required by this part, the manufacturer shall notify the FDA district office responsible for the area in which the distributor, final distributor, or multiple distributor is located of the failure of such persons to comply with the requirements of this part. Manufacturers shall have taken reasonable steps to obtain compliance by the distributor, multiple distributor, or final distributor in question before notifying FDA.

(e) A manufacturer may petition for an exemption or variance from one or more requirements of this part according to the procedures in § 821.2 of this chapter.